MAY - 7 2001

K010361

X. 510(k) SAFETY AND EFFECTIVENESS SUMMARY

Medtronic PS Medical INVISx™ Cranial Fixation System

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number: 2021898

Address of Manufacturer: Medtronic PS Medical
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1455
Fax: (805) 968-5038

Contact Person: Carol Baccash

Date: February 4, 2001

Trade or Proprietary Name: Medtronic PS Medical INVISx™ Cranial Fixation System

Common, Usual or Classification Name: Preformed nonalterable cranioplasty plate (21 CFR 882.5330)
Burr Hole Cover (21 CFR 882.5250)
Nonpowered Neurosurgical Instrument (21 CFR 882.4535)

Predicate Device Identification:
Aesculap CranioFIX Titanium Clamp System (K972332).
Sofamor Danek TiMesh System (K974017).

Device Description:
The Medtronic PS Medical INVISx™ Cranial Fixation System consists of a two piece plastic implant and associated nonpowered neurosurgical instruments. This system enables the Cranial Fixation Device to maintain strength as well as a low profile and ease of use for cranial fixation.

INVISx™ Cranial Fixation Locks are packaged sterile and are intended for single (one-time) use only. The reusable instruments are packaged nonsterile and intended to be sterilized through a standard autoclave process. The disposable instruments are packaged sterile and intended for single use only.

Intended Use:
The INVISx™ Cranial Fixation System is intended for use in refixation of cranial bone flaps after a craniotomy.

Intended Use of Predicate Device:

The Aesculap CranioFIX Titanium Clamp System and Instruments are intended for use in refixation of cranial bone flaps after craniotomy.

The Sofamor Danek TiMesh System is intended for use in any oral-maxillo-cranio-facial surgical reconstructive procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the TiMesh System is also indicated for use in reinforcing weak bony tissues in orthopedic surgical procedures such as pelvic reconstruction, acetabular reconstruction and cement restriction.

Technological Comparison:
The INVISx™ Cranial Fixation System is equivalent to the Sofamor Danek TiMesh (K974017) System and the Aesculap CranioFIX Titanium Clamp System (K972332). Substantial equivalence is based upon design, performance specifications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2001

Ms. Carol Baccash
Manager of Regulatory Compliance
Medtronic PS Medical
125 Cremona Drive
Goleta, Calilfornia 93117

Re: K010361
Trade/Device Name: INVISx Cranial Fixation System
Regulation Numbers: 21 CFR 882.5250, 888.5330
Regulatory Class: II
Product Codes: GXR, GXN
Dated: February 5, 2001
Received: February 6, 2001

Dear Ms. Baccash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: INVISx™ Cranial Fixation System 510(k) Number (if known): K01-0361

The INVISx™ Cranial Fixation System is intended for use in refixation of cranial bone flaps after a craniotomy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010361

Over the Counter Use: _____
or
Prescription Use: X
(Per 21 CFR 801.109)